REMARKS

Claims 21-30 and 32-42 are pending in the application. Claims 32-34 and 38-42 are withdrawn as being drawn to non-elected inventions. Claims 21-30 and 35-37 are under consideration. Applicants reserve the right to prosecute non-elected subject matter in subsequent divisional applications.

Objection to the Specification

The Examiner objected to the presence of references to hyperlinks and/or other forms of browser-executable code in the specification (Final Office Action, page 2). Applicants did not intend to have active links in the specification, nor to incorporate the subject matter of websites by reference to such hyperlinks. Applicants have amended the specification to remove active hyperlinks and therefore respectfully request that the Examiner withdraw the objection to the specification.

Utility Rejections under 35 U.S.C. §101 and §112, First Paragraph

Claims 21-30 and 35-37 are rejected under 35 U.S.C. §§ 101 and 112, first paragraph, based on the allegation that the claimed invention lacks patentable utility. The Final Office Action alleges in particular that "the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility" (Final Office Action, page 3). Applicants traverse the rejections for the reasons previously made of record in the response to the Office Action of January 15, 2003 and the Declarations of Furness and Bedilion.

Written description rejections under 35 U.S.C. § 112, first paragraph

Claims 21, 23, 26, 27, 28, 30, 35, and 37 have been rejected under the first paragraph of 35 U.S.C. 112 for alleged lack of an adequate written description. Applicants traverse the rejections for the reasons previously made of record in the response to the Office Action of January 15, 2003.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 21-30 and 35-37 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the Examiner states that it is not clear what is meant by the term "naturally occurring" because "all of the sequences existing in nature have not been identified" (Final Office Action, page 15). Applicants respectfully disagree and traverse the rejection for the reasons previously made of record in the response to the Office Action of January 15, 2003 and on the following grounds.

The term "naturally occurring" is a well-known term in the art which Applicants intended to be used in such context. As such, no further definition of the term is necessary (MPEP 2163 IIA3(a)):

> What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

One of ordinary skill in the art would recognize that "***a naturally occurring amino acid sequence***" as recited in claim 21 is one which occurs in nature. Through the process of natural selection, nature will have determined the appropriate amino acid sequences. Given the information provided by SEQ ID NO:12 and SEQ ID NO:25, one of skill in the art would be able to routinely obtain a polynucleotide encoding "a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:12." For example, the identification of relevant polynucleotides could be performed by hybridization and/or PCR techniques that were well-known to those skilled in the art at the time the subject application was filed and/or described throughout the Specification of the instant application. See, e.g., page 29, lines 22-33; page 40, lines 13-30; and Example VI at page 51.

Contrary to the Examiner's assertions, the Specification, as originally filed, provides adequate support for claiming polypeptides comprising a naturally occurring amino acid sequences having 90% sequence identity to SEQ ID NO:12. For example:

"HCSRP" refers to the amino acid sequences of substantially purified HCSRP obtained from any species, particularly a mammalian species, including bovine, ovine, porcine, murine, equine, and human, and from any source, whether natural, synthetic, semi-synthetic, or recombinant.
(Specification, page 9, lines 7-9)

Clearly, this definition of HCSRP encompasses naturally occurring variants of SEQ ID NO:12 from different species. The Specification further describes the identification of variants of SEQ ID NO:25.

In one aspect, hybridization with PCR probes which are capable of detecting polynucleotide sequences, including genomic sequences, encoding HCSRP or closely related molecules may be used to identify nucleic acid sequences which encode HCSRP. The specificity of the probe, whether it is made from a highly specific region, e.g., the 5' regulatory region, or from a less specific region, e.g., a conserved motif, and the stringency of the hybridization or amplification will determine whether the probe identifies only naturally occurring sequences encoding HCSRP, allelic variants, or related sequences.

Probes may also be used for the detection of related sequences, and may have at least 50% sequence identity to any of the HCSRP encoding sequences. The hybridization probes of the subject invention may be DNA or RNA and may be derived from the sequence of SEQ ID NO:14-26 or from genomic sequences including promoters, enhancers, and introns of the HCSRP gene. (Specification, at page 41, lines 13-23)

In another embodiment of the invention, nucleic acid sequences encoding HCSRP may be used to generate hybridization probes useful in mapping the naturally occurring genomic sequence. The sequences may be mapped to a particular chromosome, to a specific region of a chromosome, or to artificial chromosome constructions, e.g., human artificial chromosomes (HACs), yeast artificial chromosomes (YACs), bacterial artificial chromosomes (BACs), bacterial P1 constructions, or single chromosome cDNA libraries. (See, e.g., Harrington, J.J. et al. (1997) Nat. Genet. 15:345-355; Price, C.M. (1993) Blood Rev. 7:127-134; and Trask, B.J. (1991) Trends Genet. 7:149-154.) (Specification, at page 44, line 29 through page 45, line 1)

See also Example VI at page 51.

Naturally occurring or recombinant HCSRP is substantially purified by immunoaffinity chromatography using antibodies specific for HCSRP. An immunoaffinity column is constructed by covalently coupling anti-HCSRP antibody to an activated chromatographic resin, such as CNBr-activated SEPHAROSE (Amersham Pharmacia Biotech). After the coupling, the resin is blocked and washed according to the manufacturer's instructions.

(Specification, page 55, lines 27-31)

Therefore, one of skill in the art could readily recognize and isolate a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:12. For at least the reasons set forth above, withdrawal of the rejection under U.S.C. § 112, second paragraph is respectfully requested.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding objections/rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

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